

526 Rec'd PCT/PTO 17 OCT 2000

TRANSMITTAL LETTER THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

Attorney's Docket Number

059.0004

S. Application No.

09/622,094

International Application No.
PCT/NZ99/00016

International Filing Date
February 9, 1999

Priority Date Claimed
February 13, 1998

Title of Invention: DRUG DELIVERY SYSTEM

Applicants For DO/EO/US: Graham Francois DUIRS

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ Annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

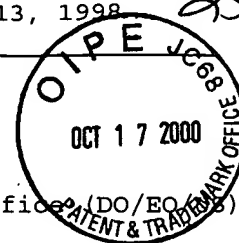
Items 11. to 16. below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
 - a. ☐ Verified Small Entity Statement.
 - b. ☒ Copy of Notification of Missing Requirements.

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U.S. APPLICATION NO.
09/622,094

INTERNATIONAL APPLICATION NO.
PCT/NZ99/00016

ATTORNEY DOCKET NUMBER
8059.0004

#3
C. Hill
85000

17. [X] The following fees are submitted:

CALCULATIONS

Basic National Fee (37 CFR 1.492(a)(1)-(5)):

Search Report has been prepared by the EPO or JPO.....\$840.00
International preliminary examination fee paid to
USPTO (37 CFR 1.482).....\$670.00
No international preliminary examination fee paid to
USPTO (37 CFR 1.482) but international search fee
paid to USPTO (37 CFR 1.445(a)(2)).....\$690.00
Neither international preliminary examination fee
(37 CFR 1.482) nor international search fee
(37 CFR 1.445(a)(2)) paid to USPTO.....\$970.00
International preliminary examination fee paid to USPTO
(37 CFR 1.482) and all claims satisfied provisions
of PCT Article 33(1)-(4).....\$ 96.00

ENTER APPROPRIATE BASIC FEE AMOUNT =

Surcharge of \$130.00 for furnishing the oath or declaration later than
[] 20 [] 30 months from the earliest claimed priority date
(37 CFR 1.492(e)).

\$130.00

| Claims | Number Filed | Number Extra | Rate |
|---|--------------|--------------|-----------|
| Total Claims | 12-20= | 0 | X \$18.00 |
| Independent Claims | 3- 3= | 3 | X \$78.00 |
| Multiple dependent claim(s) (if applicable) | | | +\$260.00 |

TOTAL OF ABOVE CALCULATIONS = \$130.00

Reduction by 1/2 for filing by small entity, if applicable. Verified
Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28)

SUBTOTAL = \$130.00

Processing fee of \$130.00 for furnishing the English translation later
than [] 20 [] 30 months from the earliest claimed priority date
(37 CFR 1.492(f)).

TOTAL NATIONAL FEE = \$130.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The
assignment must be accompanied by an appropriate cover sheet
(37 CFR 3.28, 3.31).

\$40.00 per property +
TOTAL FEES ENCLOSED = \$130.00

Amount to be
refunded \$
charged \$

- a. [X] A check in the amount of **\$130.00** to cover the above fees is enclosed.
b. [] Please charge my Deposit Account No. _____ in the amount of \$ _____
to cover the above fees. A duplicate copy of this sheet is enclosed.
c. [X] The Commissioner is hereby authorized to charge any additional fees
which may be required, or credit any overpayment to Deposit Account
No. 06-0916. A duplicate copy of this sheet is enclosed.

The Commissioner is hereby authorized to charge any other fees due under 37 C.F.R. §1.16
or §1.17 during the pendency of this application to our Deposit Account No. 06-0916.

SEND ALL CORRESPONDENCE TO:
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Garrett & Dunner, L.L.P.
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DWH/FPD/sci

David W. Hill
David W. Hill
Reg. No. 28,220

Submitted: October 17, 2000

DECLARATION AND POWER OF ATTORNEY

Attorney Docket No. _____

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: Drug Delivery System

and/or ☐ was filed on 11 August 2000 as United States Application Serial No. _____ the specification of which ☐ is attached
No. _____ and was amended on _____ (if applicable) or PCT International Application

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate or § 365(a) of any PCT International application(s) designating at least one country other than the United States, listed below and have also identified below, any foreign application(s) for patent or inventor's certificate, or any PCT International application(s) having a filing date before that of the application(s) of which priority is claimed:

| Country | Application Number | Date of Filing | Priority Claimed Under 35 U.S.C. |
|-------------|--------------------|------------------|--|
| New Zealand | 329799 | 13 February 1998 | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| PCT | 334795 | 18 November 1998 | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| | PCT/NZ99/00016 | 9 February 1999 | <input type="checkbox"/> YES <input type="checkbox"/> NO |

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

| Application Number | Date of Filing |
|--------------------|----------------|
| | |
| | |

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) or § 365(c) of any PCT International application(s) designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application(s) in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application(s) and the national or PCT International filing date of this application:

| Application Number | Date of Filing | Status (Patented, Pending, Abandoned) |
|--------------------|----------------|---------------------------------------|
| | | |

I hereby appoint the following attorney and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected herewith. FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P., Douglas B. Henderson, Reg. No. 20,291; Ford F. Farabow, Jr., Reg. No. 20,630; Arthur S. Garrett, Reg. No. 20,338; Donald R. Dunner, Reg. No. 19,073; Brian G. Brunsvold, Reg. No. 22,593; Tipton D. Jennings, IV, Reg. No. 20,645; Jerry D. Voight, Reg. No. 23,020; Laurence R. Hefter, Reg. No. 20,827; Kenneth E. Payne, Reg. No. 23,098; Herbert H. Mintz, Reg. No. 26,691; C. Larry O'Rourke, Reg. No. 26,014; Albert J. Santorelli, Reg. No. 22,610; Michael C. Elmer, Reg. No. 25,857; Richard H. Smith, Reg. No. 20,609; Stephen L. Peterson, Reg. No. 26,325; John M. Romary, Reg. No. 26,331; Bruce C. Zotter, Reg. No. 27,680; Dennis P. O'Relley, Reg. No. 27,932; Allen M. Sokal, Reg. No. 26,695; Robert D. Bajefsky, Reg. No. 25,387; Richard L. Stroup, Reg. No. 28,478; David W. Hill, Reg. No. 28,220; Thomas L. Irving, Reg. No. 28,619; Charles E. Lipsey, Reg. No. 28,165; Thomas W. Winland, Reg. No. 27,605; Basil J. Lewis, Reg. No. 28,818; Martin B. Racine, Reg. No. 30,415; Thomas H. Jenkins, Reg. No. 30,857; Robert E. Converse, Jr., Reg. No. 27,432; Clair X. Mullen, Jr., Reg. No. 20,348; Christopher P. Foley, Reg. No. 31,354; John C. Paul, Reg. No. 30,413; Roger D. Taylor, Reg. No. 28,992; David M. Kelly, Reg. No. 30,953; Kenneth J. Meyers, Reg. No. 25,146; Carol P. Einaudi, Reg. No. 32,220; Walter Y. Boyd, Jr., Reg. No. 31,738; Steven M. Anzalone, Reg. No. 32,095; Jean B. Fordis, Reg. No. 32,984; Barbara C. McCurdy, Reg. No. 32,120; James K. Hammond, Reg. No. 31,964; Richard V. Burguljan, Reg. No. 31,744; J. Michael Jakes, Reg. No. 32,824; Thomas W. Banks, Reg. No. 32,719; Christopher P. Isaac, Reg. No. 32,616; Bryan C. Diner, Reg. No. 32,409; M. Paul Barker, Reg. No. 32,013; Andrew Chanhon Sonu, Reg. No. 33,457; David S. Forman, Reg. No. 33,694; Vincent P. Kovalick, Reg. No. 32,867; James W. Edmondson, Reg. No. 33,871; Michael R. McGurk, Reg. No. 32,045; Joann M. Neth, Reg. No. 36,363; Gerson S. Panltch, Reg. No. 33,751; Cheri M. Taylor, Reg. No. 33,216; Charles E. Van Horn, Reg. No. 40,266; Linda A. Wadler, Reg. No. 33,218; Jeffrey A. Berkowitz, Reg. No. 36,743; Michael R. Kelly, Reg. No. 33,921; James B. Monroe, Reg. No. 33,971; Doris Johnson Hines, Reg. No. 34,629; Allen R. Jensen, Reg. No. 28,224; Lori Ann Johnson, Reg. No. 34,498; and David A. Manspelzer, Reg. No. 37,540 and

and David A. Manspelzer, Reg. No. 37,540 and _____ Please address all correspondence to FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 1300 I Street, N.W., Washington, D.C. 20005, Telephone No. (202) 408-4000.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

| | | | |
|-----------------------------|---|----------------------|----------------------------|
| Full Name of First Inventor | Graham Francois Duirs | Inventor's Signature | Date |
| Residence | 17 MacFarlane Street, Hamilton, New Zealand | | 11.9.2000 |
| Post Office Address | | | Citizenship New Zealand |

Listing of Inventors Continued on Page 2 hereof. ☐ Yes ☐ No

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

January 2000